U.S. Food and Drug Administration
Center for Drug Evaluation and Research

Guidance Documents

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Most of these documents are in Adobe Acrobat format, also known as PDF. The free upgrade to Adobe Acrobat 4.0 or higher is recommended, especially if you have difficulty opening any of the documents below. Another method of obtaining guidance documents is through the Division of Drug Information.

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- FDA's Good Guidance Practices regulation of September 19, 2000. Optional Format: PDF.
- Comprehensive List of Guidance Documents (9/11/2002)
- Guidance Agenda: Guidances CDER is Planning to Develop During Fiscal Year 2003 (10/21/2002)
- New/Revised/Withdrawn List for 2000 (5/24/2001)
- New/Revised/Withdrawn List (9/23/2002)

Advertising

1. Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling (Issued 12/1997, Posted

1/12/1998)
2. Consumer-Directed Broadcast Advertisements [HTML] or [PDF] (Issued 8/1999, Posted 8/6/1999)
   Questions and Answers (Posted 8/6/1999)
3. Industry-Supported Scientific and Educational Activities [HTML] or [PDF] (Issued 12/3/1997, Posted 12/4/1997)

Advertising Draft

1. Accelerated Approval Products: Submission of Promotional Materials (Posted 3/26/1999)
2. Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling (Issued 1/1999, Posted 3/12/1999)
3. Promoting Medical Products in a Changing Healthcare Environment: I. Medical Product Promotion by Healthcare Organizations or Pharmacy Management Companies (PBMs) (Issued 12/1997. Posted 1/5/1998)
4. Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements [HTML] or [PDF] (Issued 4/2001, Posted 4/20/2001]

Biopharmaceutics

1. Bioanalytical Method Validation [HTML] or [PDF] (Issued 5/2001, Posted 5/22/2001)
2. Cholestyramine Powder in Vitro Bioequivalence (Intermin Guidance)
3. Bioavailability and Bioequivalence Studies for Orally Administered Drug Products ? General Considerations (Issued 10/2000, Posted 8/22/2002)

4. Clozapine Tablets in Vivo Bioequivalence and in Vitro Dissolution Testing (Issued 11/15/1996, Reposted 10/15/1998)
5. Corticosteroids, Dermatologic (topical) In Vivo (Issued 6/2/1995, Posted 3/6/1998)
6. Dissolution Testing of Immediate Release Solid Oral Dosage Forms or WordPerfect 6.x Version (Issued 8/1997, Posted 8/25/1997)
7. Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (Issued 9/1997, Posted 9/26/1997)
8. Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro (Issued 6/27/1989, Posted 3/2/1998)
9. Phenytoin/Phenytion Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing (Issued 3/4/1994, Posted 3/2/1998)
10. Potassium Chloride (slow-release tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing (Revised 6/6/1994, Posted 6/22/1998)
11. Statistical Approaches to Establishing Bioequivalence [HTML] or [PDF] (Issued 2/2001, Posted 2/1/2001)
12. Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. Optional Format: PDF. (Issued 8/2000, Posted 8/31/2000)

Biopharmaceutics (Draft)

1. Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (Issued 6/1999, Posted 6/2/1999) - Statistical Information for In Vitro Bioequivalence Data (Issued 8/1999, Posted 8/18/1999)
2. Bioavailability and Bioequivalence Studies for Orally Administered Drug Products ? General Considerations [HTML] or [PDF] (Issued 7/2002, Posted 7/2002)
3. Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence [HTML] or [PDF] (Issued 3/6/2000, Posted 3/6/2000)
4. Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling (Issued 11/2001, Posted 11/28/2001)
5. In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Studies (Issued 12/10/1997, Posted 12/10/1997) Bioequivalence Studies Data and Detailed Statistical Methodology (Posted 3/2/1998)

Chemistry

1. BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation [HTML] or [PDF] (Issued 2/2001, Posted 2/16/2001)
2. Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products (Issued 7/1997, Posted 7/28/1997)
3. Changes to an Approved NDA or ANDA [HTML] or [PDF] (Issued 11/1999, Posted 11/19/1999)
4. Changes to an Approved NDA or ANDA: Questions and Answers [HTML] or [PDF] (Issued 1/2001, Posted 1/22/2001)
5. Container Closure Systems for Packaging Human Drugs and Biologics [HTML] or [PDF] (Issued 5/1999, Posted 7/6/1999)
   - Container Closure Systems for Packaging Human Drugs and Biologics -- Questions and Answers [PDF] (Issued 5/2002, Posted 5/10/2002)
6. Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products
7. Development of New Stereoisomeric Drugs (5/1/1992) (Post Date: 1/3/1996)
8. Drug Master Files (9/1/1989)
   Current DMF Information (e.g. lists, addresses, etc.)
9. Drug Master Files for Bulk Antibiotic Drug Substances [PDF] or [Word] (Issued 11/1999, Posted 11/26/1999)
10. Environmental Assessment of Human Drug and Biologics Applications (Issued 7/1998, Posted 7/24/98)
11. Format and Content of the Chemistry, Manufacturing and Controls Section of an Application* (Issued 2/1987, Posted 3/2/1998)
12. Format and Content for the CMC Section of an Annual Report (9/1/1994)
13. IND Meetings for Human Drugs and Biologics Chemistry, Manufacturing, and Controls Information [HTML] or [PDF] (Issued 5/2001, Posted 6/4/2001)
14. Monoclonal Antibodies Used as Reagents in Drug Manufacturing [HTML] or [PDF] (Issued 3/2001, Posted 3/28/2001)

15. Nasal Spray and Inhalation Solution, Suspension, and Drug Products [HTML] or [PDF] (Issued 7/2002, Posted 7/3/2002)
16. NDAs: Impurities in Drug Substances [HTML] or [PDF] (Issued 2/2000, Posted 2/24/2000)
17. PAC-ATLS: Postapproval Changes - Analytical Testing Laboratory Sites (Issued 4/28/1998, Posted 4/28/1998)
18. The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) (12/20/2000)

19. SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation
20. SUPAC-IR Questions and Answers about SUPAC-IR Guidance (2/18/1997)
21. SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum (Issued 1/1999, Posted 2/25/1999)
22. SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation (Issued 10/6/1997, Posted 10/6/1997)
23. SUPAC-SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation (Issued 5/1997; Posted 6/16/1997)
24. Reviewer Guidance, Validation of Chromatographic Methods
25. Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products
26. Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances
27. Submitting Documentation for the Manufacturing of and Controls for Drug Products* [HTML] or [PDF] (Issued 2/1987, Posted 3/2/1998)
28. Submitting Documentation for the Stability of Human Drugs and Biologics* (Issued 2/1987, Posted 3/2/1998)
29. Submitting Samples and Analytical Data for Methods Validation
30. Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances

Chemistry (Draft)

1. Analytical Procedures and Methods Validation. Optional format: PDF. (Issued 8/2000, Posted 8/30/2000)
2. Botanical Drug Products. Optional format: PDF. (Issued 8/2000, Posted 8/10/2000)
3. INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products Chemistry, Manufacturing, and Controls Content and Format (Issued 2/1999, Published 4/19/1999)
4. Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products [HTML] or [PDF] or (Issued 11/13/1998, Posted 11/19/1998, HTML Posted 9/27/1999)
5. Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation. (Issued 7/2002, Posted 8/20/2002)
6. Stability Testing of Drug Substances and Drug Products (Issued 6/5/1998, Posted 6/8/1998)

7. SUPAC-SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum (Issued 12/1998, Posted 1/5/1999)

Clinical/Antimicrobial

1. Antiretroviral Drugs Using Plasma HIV RNA Measurements ? Clinical Considerations for Accelerated and Traditional Approval [Word] or [PDF] (Issued 10/2002, Posted 10/31/2002)
2. Clinical Development and Labeling of Anti-Infective Drug Products [HTML] or [PDF] (Issued 10/1992, Posted 3/2/1998, Revised 2/12/2001)
3. Clinical Evaluation of Anti-Infective Drugs (Systemic) (Issued 9/77, Posted 3/2/1998)
4. Preclinical Development of Antiviral Drugs

Clinical/Antimicrobial (Draft)

1. Acute Bacterial Exacerbation of Chronic Bronchitis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
2. Acute Bacterial Meningitis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
3. Acute Bacterial Sinusitis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
4. Acute or Chronic Bacterial Prostatitis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
5. Acute Otitis Media ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
6. Bacterial Vaginosis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
7. Catheter-Related Bloodstream Infections - Developing Antimicrobial Drugs for Treatment [HTML] or [PDF] (Issued 10/1999, Posted 10/18/1999)
8. Community-Acquired Pneumonia ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
9. Complicated Urinary Tract Infections and Pyelonephritis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998) [HTML] or [PDF]
10. Developing Antimicrobial Drugs ? General Considerations for Clinical Trials (Issued 7/22/1998, Posted 7/22/1998) [Main Document]
11. Empiric Therapy of Febrile Neutropenia ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
12. Evaluating Clinical Studies Of Antimicrobials In The Division Of Anti-Infective Drug Products (2/18/1997)
13. Inhalational Anthrax (Post Exposure) -- Developing Antimicrobial Drugs (Issued 3/15/2002, Posted 3/15/2002) [HTML] or [PDF]
14. Lyme Disease ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
15. Nosocomial Pneumonia ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
16. Secondary Bacterial Infections of Acute Bronchitis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)

17. Streptococcal Pharyngitis and Tonsillitis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
18. Uncomplicated and Complicated Skin and Skin Structure Infections ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
19. Uncomplicated Gonorrhea ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
20. Uncomplicated Urinary Tract Infections ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
21. Vulvovaginal Candidiasis ? Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)

Clinical/Medical

1. Acceptance of Foreign Clinical Studies [HTML] or [PDF] (Posted 3/12/2001)
2. Cancer Drug and Biological Products - Clinical Data in Marketing Applications [HTML] or [PDF] (Posted 10/11/2001)
3. Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (Issued 1/1999, Posted 2/16/1999) [HTML] or [PDF]
4. Clinical Development Programs for MDI and DPI Drug Products (Issued 9/19/1994, Posted 3/2/1998)
5. Clinical Evaluation of Analgesic Drugs (Issued 12/1992, Posted 3/2/1998)
6. Clinical Evaluation of Antacid Drugs (Issued, 4/1/78, Posted 3/2/1998)
7. Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children)
8. Clinical Evaluation of Antianxiety Drugs (Issued 9/77, Posted 3/2/1998)
9. Clinical Evaluation of Antidepressant Drugs (Issued 9/77, Posted 3/2/1998)
10. Clinical Evaluation of Antidiarrheal Drugs (Issued 9/77, Posted 3/2/1998)
11. Clinical Evaluation of Antiepileptic Drugs (adults and children) (Issued 1/1981, Posted 3/2/1998)
12. Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs (Issued 9/77, Posted 3/2/1998)
13. Clinical Evaluation of General Anesthetics (Issued 5/1982, Posted 3/2/1998)
14. Clinical Evaluation of Hypnotic Drugs (Issued 9/77, Posted 3/2/1998)
15. Clinical Evaluation of Laxative Drugs (Issued 4/78, Posted 3/2/1998)
16. Clinical Evaluation of Local Anesthetics (Posted 3/2/1998)
17. Clinical Evaluation of Psychoactive Drugs in Infants and Children (Posted 3/2/1998)
18. Clinical Evaluation of Radiopharmaceutical Drugs (Posted 3/2/1998)
19. Content and Format for Pediatric Use Supplements
20. Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products
21. Establishing Pregnancy Exposure Registries [Word] or [PDF] (Issued 8/2002, Posted 9/20/2002)
22. FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products [HTML] or [PDF] (Issued 12/1998, Posted 2/2/1999, HTML posted 9/14/1999)

23. FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer (Posted 3/2/1998)
24. FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer (Posted 3/2/1998)
25. Format and Content of the Clinical and Statistical Sections of an Application (Issued 7/1988, Posted 5/21/1997)
26. Format and Content of the Summary for New Drug and Antibiotic Applications* (Issued 2/1987, Posted 3/2/1998)
27. Formatting, Assembling and Submitting New Drug and Antibiotic Applications* (Issued 2/1987, Posted 3/2/1998)
28. General Considerations for the Clinical Evaluation of Drugs
29. General Considerations for the Clinical Evaluation of Drugs in Infants and Children (Issued 9/77, Posted 3/2/1998)
30. Guidance for the Development of Vaginal Contraceptive Drugs (NDA) (Posted 3/2/1998)
31. Levothyroxine Sodium Tablets - In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing [HTML] or [PDF] (Issued 2/2001, Posted 3/8/2001)
32. Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer (Posted 3/2/1998)
33. Oncologic Drugs Advisory Committee Discussion on FDA Requirements or Approval of New Drugs for Treatment of Colon and Rectal Cancer (Posted 3/2/1998)
34. Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report or WordPerfect 6.x version (Issued 8/27/1997, Posted 8/27/1997)
35. Postmarketing Reporting of Adverse Drug Experiences (Issued 3/1992, Posted 3/2/1998)
36. Preclinical Development of Immunomodulatory Drugs for Treatment of HIV Infection and Associated Disorders (Reposted 1/21/1999)
37. Preparation of Investigational New Drug Products (Human and Animal) (Issued 11/1992, Posted 3/2/1998)
38. Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (Issued 5/14/1998, Posted 5/14/1998)
39. Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (Issued 7/22/1993, Posted 3/2/1998)
40. Study of Drugs Likely to be used in the Elderly (Issued 11/1989, Posted 3/2/1998)
41. Submission of Abbreviated Reports and Synopses in Support of Marketing Applications [HTML] or [PDF] (Issued 8/1999, Posted 9/13/1999)

Clinical/Medical (Draft)

1. Allergic Rhinitis: Clinical Development Programs for Drug Products [HTML] or [PDF] (Issued 6/2000, Posted 6/20/2000)
2. Available Therapy [HTML] or [PDF] (Posted 2/6/2002)
3. Chronic Cutaneous Ulcer and Burn Wounds ? Developing Products for Treatment [HTML] or [PDF] (Issued 6/2000, Posted 6/27/2000)
4. Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis [Word] or [PDF] (Issued 7/07/1999, Posted 7/14/1999)
5. Clinical Evaluation of Lipid-Altering Agents (Issued 10/1990, Posted 2/18/1998)

6. Clinical Evaluation of Weight-Control Drugs (9/24/1996, Posted 2/18/1998)
7. Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Dada Monitoring Committees [HTML] or [PDF] (11/15/2001)
8. Developing Medical Imaging Drugs and Biologics [HTML] or [PDF] (Issued 7/2000, Posted 7/28/2000)
9. Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis [HTML] or [PDF] (Issued 5/2000, Posted 6/13/2000)
10. Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals [HTML]or [PDF] (Issued 9/6/2002)
11. Establishing Pregnancy Registries (Issued 6/2/1999, Posted 6/2/1999)
12. Evaluation of Human Pregnancy Outcome Data [HTML] or [PDF] (Issued 6/2/1999, Posted 6/8/99)
13. Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children [HTML] or [PDF] (Posted 11/6/2001)
14. Exercise-Induced Bronchospasm (EIB) ? Development of Drugs to Prevent EIB [PDF] (Issued 2/2002, Posted 2/19/2002)
15. Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment [HTML] or [PDF] (Issued 5/2000, Posted 5/18/2000)
16. Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (3/31/2000)
17. IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Products [PDF] (Issued 4/2002, Posted 4/9/2002)
18. Inhalation Drug Products Packaged in Semipermeable Container Closure Systems [PDF] (Issued 7/2002, Posted 7/25/2002)
19. ntegration of Dose-Counting Mechanisms into MDI Drug Products [PDF] (Issued 12/2001, Posted 12/10/2001)
20. OTC Treatment of Herpes Labialis with Antiviral Agents [HTML] or [PDF] (Issued 3/8/2000, Posted 3/8/2000)
21. Pediatric Oncology Studies In Response to a Written Request [HTML] or [PDF] (Issued 6/2000, Posted 6/19/2000)
22. Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis (Issued 4/1994, Posted 2/18/1998)
23. Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)) [HTML] or [PDF] (Posted 12/1/2000)

Clinical Pharmacology

1. Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (Issued 4/1997, Posted 4/8/1997)
2. Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application* (Issued 2/1987, Posted 3/2/1998)
3. In Vivo Drug Metabolism/Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling [HTML] or [PDF] (Issued 11/24/1999, Posted 11/24/1999)
4. Pharmacokinetics in Patients with Impaired Renal Function (Issued 5/14/1998, Posted 5/14/1998)
5. Population Pharmacokinetics (Issued 2/1999, Posted 2/10/1999)

Clinical Pharmacology (Draft)

1. Exposure-Response Relationships: Study Design, Data Analysis, and Regulatory Applications [PDF] (Issued 4/1/2002, Posted 4/1/2002)
2. General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products (Issued 11/1998, Posted 11/12/1998)
3. Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling [HTML] or [PDF] (Issued 11/1999, Posted 12/6/1999)

Compliance

1. A Review of FDA's Implementation of the Drug Export Amendments of 1986 (Issued 11/1989, Posted 3/2/1998)
2. Compressed Medical Gases (Issued 2/1989, Posted 3/10/1997)
3. Computerized Systems Used in Clinical Trials [HTML] - [Acrobat Version] (Issued 4/1999, Posted 5/11/1999)
4. General Principles of Process Validation
5. Good Laboratory Practice Regulations Questions and Answers (Posted 3/2/1998)
6. Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities - FDA Public Health Advisory [HTML] or [PDF] (Issued and Posted 4/5/2001)
7. Guideline for Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices (Posted 3/2/1998)
8. Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (Issued 6/27/1997, Posted 6/27/1997)
9. Monitoring of Clinical Investigations (Posted 3/2/1998)
10. Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment (Posted 3/2/1998)
11. Possible Dioxin/PCB Contamination of Drug and Biological Products [HTML] or [PDF] (Issued 8/23/1999, Posted 8/23/1999)
12. Street Drug Alternatives [HTML] or [PDF] (Issued 3/2000, Posted 3/31/2000)
13. Sterile Drug Products Produced by Aseptic Processing (Issued 6/1987, Posted 3/2/1998)

Compliance (Draft)

1. Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (21 CFR 50.24) Draft released for comment 3/30/2000 (5/12/2000)
2. Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production (Issued 9/30/1998, Posted 9/30/1998)
3. Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients (Issued 4/17/1998, Posted 4/17/1998)
4. PET Drug Products - Current Good Manufacturing Practice (CGMP) [HTML] or [PDF] (Issued 3/29/2002, Posted 3/29/2002)

5. Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics [HTML] or [PDF] (Issued 6/2002, Posted 6/27/2002)

Electronic Submissions

1. Providing Regulatory Submissions in Electronic Format ? ANDAs [HTML] or [PDF] (Issued 6/2002, Posted 6/27/2002)
2. Regulatory Submissions in Electronic Format; General Considerations (Issued 1/1999, Posted 1/27/1999)
3. Regulatory Submissions in Electronic Format; New Drug Applications (Issued 1/1999, Posted 1/27/1999)

Example of an Electronic New Drug Application Submission (Posted 2/17/1999).

Electronic Submissions Draft

1. Electronic Records; Electronic Signatures Electronic Copies of Electronic Records [PDF] (Issued 11/2002, Posted 11/12/2002)
2. Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports [HTML] or [PDF] (Issued 5/2001, Posted 5/3/2001)
3. Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising and Promotional Labeling [HTML] or [PDF] (Issued 1/2001, Posted 1/30/2001)

Generics

1. Alternate Source of the Active Pharmaceutical Ingredient in Pending ANDAs [HTML] or [PDF] (Posted 12/12/2000)
2. ANDA's: Impurities in Drug Substances [HTML] or [PDF] (Issued 11/1999, Posted 12/2/1999)
3. Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act [HTML] or [PDF] (Posted 3/27/2000)
4. Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past. (Posted 3/2/1998)
5. Letter describing efforts by the CDER and the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new and abbreviated drug approval process in order to reduce duplication or redundancy in the process (Posted 3/2/1998)
6. Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy (Posted 3/2/1998)
7. Letter on the Provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters (Posted 3/2/1998)
8. Letter on the provision of new procedures and policies affecting the generic drug review process (Posted 3/2/1998)

9. Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions (Posted 3/2/1998)
10. Letter on the response to 12/20/1984 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act (Posted 3/2/1998)
11. Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law (Posted 3/2/1998)
12. Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria and bioequivalence requirements (Posted 3/2/1998)
13. Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications [PDF] (Issued 12/2001, Posted 12/20/2001)
14. Organization of an ANDA (Issued 2/1999, 3/2/1999)
15. Revising ANDA Labeling Following Revision of the RLD Labeling [HTML] or [PDF] (Issued 4/26/2000, 4/26/2000)
16. Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products [HTML] or [PDF] (Issued 12/1999, Posted 2/3/2000)
17. Variations in Drug Products that May Be Included in a Single ANDA (Issued 12/1998, Posted 1/26/1999)

Generics (Draft)

1. ANDAs: Impurities in Drug Products (Issued 12/1998, Posted 1/5/1999)
2. Content and Format of an Abbreviated New Drug Application (ANDA) - Positron Emission Tomography (PET) Drug Products With specific information for ANDAs for Fludeoxyglucose F18 Injection (Issued 4/1997, Posted 4/23/1997)
3. Handling and Retention of BA and BE Testing Samples (Issued 8/2002, Posted 8/20/2002)
4. Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing [PDF] (Issued 8/2002, Posted 8/6/2002)

Good Review Practices (GRPs)

1. Pharmacology/Toxicology Review Format [PDF] (Posted 5/9/2001)

Good Review Practices (GRPs) (Draft)

1. Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review (11/1996)

Industry Letters

1. Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program (Posted 3/2/1998)
2. Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required (Posted 3/2/1998)
3. Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I (Posted 3/2/1998)
4. Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance (Posted 3/2/1998)
5. Implementation Plan USP injection nomenclature (Posted 3/2/1998)
6. Seventh of a series of letters about the Act providing guidance on the "130-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C (Posted 3/2/1998)
7. Sixth of a series of informal notice letters about the Act discussing 3-and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505 (j)(4)(D) of the FD&C Act (Posted 3/2/1998)
8. Supplement to 10/11/1984 letter about policies, procedures and implementation of the Act (Q&A format) (Posted 3/2/1998)
9. Third of a series of letters regarding the implementation of the Act (Posted 3/2/1998)
10. Year 2000 Letter from Dr. Janet Woodcock (10/19/98)

International Conference on Harmonisation

Safety

1. S1A The Need for Long-term Rodent Carcinogenicity Studies of Pharmaceuticals
2. S1B Testing for Carcinogenicity of Pharmaceuticals (Issued 2/28/1998, Posted 3/24/1998)
3. S1C Dose Selection for Carcinogenicity Studies of Pharmaceuticals
4. S1C(R) Guidance on Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes (Issued 12/4/1997, Posted 12/11/1997)
5. S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals
6. S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals (Issued 11/21/1997, Posted 5/4/1998)
7. S3A Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies
8. S3B Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies
9. S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) [PDF] or [Text] Posted 6/25/99
10. S5A Detection of Toxicity to Reproduction for Medicinal Products (Issued 9/1994, Posted 4/23/1997)
11. S5B Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility
12. S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (Issued 11/1997, Posted 11/18/1997)
13. S7A Safety Pharmacology Studies for Human Pharmaceuticals [HTML] or [PDF] (Issued 7/2001, Posted 7/12/2001)

Joint Safety/Efficacy (Multidisciplinary)

1. M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals (Issued 11/1997, Posted 11/25/1997)
2. M4: Common Technical Document for the Registration of Pharmaceuticals for Human Use (Posted 10/15/2001)
   - M4: Organization of the CTD [HTML] or [PDF]
   - M4: The CTD -- Quality [HTML] or [PDF]
   - M4: The CTD -- Efficacy [HTML] or [PDF]
   - M4: The CTD -- Safety [HTML] or [PDF]
   - M4: The CTD -- Safety Appendices [HTML] or [WORD] or [PDF]

Efficacy

1. E1A The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions
2. E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
3. E2B International Conference on Harmonisation; Guidance on Data Elements for Transmission of Individual Case Safety Reports (Issued 1/15/1998, Posted 1/15/1998)
   - E2BM Data Elements for Transmission Of Individual Case Safety Reports (Issued 4/2002, Posted 4/4/2002)
4. E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (Issued 5/19/1997, Posted 3/19/1998)
5. E3 Structure and Content of Clinical Study Reports
6. E4 Dose-Response Information to Support Drug Registration
7. E5 Ethnic Factors in the Acceptability of Foreign Clinical Data (Issued 6/10/1998, Posted 6/10/1998)
8. E6 Good Clinical Practice: Consolidated Guideline Spanish Version (Issued 5/9/1997, Posted 3/19/1998)
9. E7 Studies in Support of Special Populations: Geriatrics
10. E8 General Considerations for Clinical Trials (Issued 12/1997, Posted 12/17/1997)
11. E9 Statistical Principles for Clinical Trials (9/1/1998)
12. E 10 Choice of Control Group and Related Issues in Clinical Trials [HTML] or [PDF] (Issued 5/2001, Posted 5/11/2001)
13. E11 Clinical Investigation of Medicinal Products in the Pediatric Population [Acrobat] (Issued 12/2000, Posted 12/14/2000)

Quality

1. Q1A(R) Stability Testing of New Drug Substances and Products [HTML] or [PDF] (Posted 11/6/2001)
2. Q1B Photostability Testing of New Drug Substances and Products [HTML] or [PDF] (Issued 11/1996, Reposted 7/7/1998)

3. Q1C Stability Testing for New Dosage Forms (Issued 5/9/1997, Posted 3/19/1998)
4. Q2A Text on Validation of Analytical Procedures
5. Q2B Validation of Analytical Procedures: Methodology (Issued 5/19/1997, Posted 3/19/1997)
6. Q3A Impurities in New Drug Substances
7. Q3B Impurities in New Drug Products or Adobe Acrobat version (Issued 5/19/1997, Reposted 7/7/1998)
8. Q3C Impurities: Residual Solvents or Adobe Acrobat version (Issued 12/24/1997, Posted 12/30/1997)
   Q3C Tables and List or Adobe Acrobat version (Posted 10/2/2001).
   Appendix 4, Appendix 5, and Appendix 6 (Appendices were issued with the Q3C draft guidance documents)
   Maintenance Procedures for Updating (Posted 2/11/2002)
9. Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin (Posted 9/1998)
10. Q5B Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products
11. Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products
12. Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability (Issued 9/21/1998, Posted 9/21/1998)
13. Q6A International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances. [Text] or [PDF] (12/29/2000)
14. Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products [PDF] (Issued 8/1999, Posted 12/14/2001)
15. Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients [HTML] or [PDF] (Issued 8/2001, Posted 9/24/2001]

International Conference on Harmonisation (Draft)

Efficacy

1. Principles for Clinical Evaluation of New Antihypertensive Drugs. Optional Format: PDF. (Issued 8/2000, Posted 8/8/2000)

Joint Safety/Efficacy (Multidisciplinary) (Draft)

1. M2 Electronic Common Technical Document Specification [HTML] or [PDF] (Issued 6/2002, Posted 6/13/2002)
2. Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (Issued 9/2001, Posted 9/5/2001) [PDF]

Quality

1. Q1D Bracketing and matrixing designs for stability testing of drug substances and drug products [HTML] or [PDF] (Posted 9/25/2001)
2. Q3A(R) Impurities in New Drug Substances [HTML] or [PDF]
3. Q3B(R) Impurities in New Drug Products [Text] or [PDF] (Issued 7/2000, Posted 7/19/2000)
4. Q1E Evaluation of Stability Data [HTML] or [PDF] (Issued 6/2002, Posted 6/13/2002)
5. Q1F Stability Data Package for Registration in Climatic Zones III and IV [HTML] or [PDF] (Issued 6/2002, Posted 6/13/2002)

Safety

1. S7B Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals [HTML] or [PDF] (Issued 6/2002, Posted 6/13/2002)

Investigational New Drug Applications

1. Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs

Labeling

The unlinked guidance's below have been withdrawn. See Federal Register Notice from July 5, 2002 : [Text] or [PDF]

1. Acetaminophen, Aspirin and Codeine Phosphate Tablets and Acetaminophen, Aspirin and Codeine Phosphate Capsules
2. Acetaminophen and codeine Phosphate Oral Solution and oral suspension (Issued 12/1993, Posted 7/11/1997)
3. Alprazolam Tablets or WordPerfect 6.x Version (Issued 8/1996, Posted 8/21/1997)
4. Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP (Issued 9/1997, Posted 10/16/1997)
5. Amlodipine Besylate Tablets (Issued 9/1997, Posted 10/15/1997)
6. Astemizole Tablets (Issued 9/1997, Posted 10/15/1997)
7. Atenolol Tablets or WordPerfect 6.x Version (Issued 8/1997, Posted 8/21/1997)
8. Butalbital, Acetaminophen and Caffeine Tablets USP, Butalbital, Acetaminophen and Caffeine Capsules USP (Issued 9/1997, Posted 10/16/1997)
9. Butalbital, Acetaminophen, Caffeine and Hydrocodone Bitartrate Tablets (Issued 9/1997, Posted 10/16/1997)
10. Butorphanol Tartrate Injection USP

11. Captopril and Hydrochlorothiazide Tablets, USP
12. Captopril Tablets (Issued 2/1995, Posted 7/11/1997)
13. Carbidopa and Levodopa Tablets USP
14. Cimetidine Hydrochloride Injection (Issued 9/1995, Posted 7/11/1997)
15. Cimetidine Tablets, USP
16. Cisapride Oral Suspension (Issued 9/1997, Posted 10/16/1997)
17. Cisapride Tablets (Issued 9/1997, Posted 10/20/1997)
18. Clindamycin Phosphate Injection USP (Revised 9/1998, Posted 10/15/1998)
19. Content and Format for Geriatric Labeling [HTML] or [PDF] (Issued 10/2001, Posted 10/4/2001)
20. Diclofenac Sodium Delayed-release Tablets
21. Diltiazem Hydrochloride Extended-release Capsules
22. Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution, USP
23. Diphenoxylate Hydrochloride and Atropine Sulfate Tablets, USP
24. Fludeoxyglucose F18 Injection (Issued 1/1997, Posted 3/1/1997)
25. Flurbiprofen Tablets USP
26. Fluvoxamine Maleate Tablets (Issued 9/1997, Posted 10/20/1997)
27. Gentamicin Sulfate Ophthalmic Solution USP and Gentamicin Sulfate Ophthalmic Ointment USP
28. Heparin Sodium Injection, USP
29. Hydrocodone Bitartrate and Acetaminophen Tablets USP
30. Indomethacin Capsules, USP
31. Itraconazole Capsules (Isssued 9/1998, Posted 10/15/1998)
32. Leucovorin Calcium for Injection (Issued 7/1996, Posted 7/11/1997)
33. Leucovorin Calcium Tablets USP (Issued 7/1996, Posted 7/11/1996)
34. Medroxyprogesterone Acetate Tablets, USP (Revised 9/1998, Posted 10/15/1998)
35. Metaproternol Sulfate Inhalation Solution USP
36. Metaproterenol Sulfate Syrup, USP
37. Metaproterenol Sulfate Tablets, USP
38. Metoclopramide Tablets USP and Metoclopramide Oral Solution USP
39. Naproxen Sodium Tablets USP (Issued 9/1997, Posted 10/16/1997)
40. Naproxen Tablets USP (Issued 9/1997, Posted 10/16/1997)
41. Paclitaxel Injection (Issued 9/1997, Posted 10/15/1997)
42. Quinidine Sulfate Tablets USP (Issued 10/1995, Posted 7/11/1997)
43. Ranitidine Tablets USP
44. Risperidone Oral Solution (Issued 9/1997, Posted 10/15/1997)
45. Risperidone Tablets (Issued 9/1997, Posted 10/15/1997)
46. Sulfacetamide Sodium Ophthalmic Solution USP and Sulfacetamide Sodium Ophthalmic Ointment USP
47. Sulfacetamide Sodium and Prednisolone Acetate

48. Sulfamethoxazole and Trimethoprim Tablets USP and Sulfamethoxazole and Trimethoprim Oral Suspension USP
49. Theophylline
50. Theophylline Intravenous Dosage Forms (Issued 9/1/1995, Posted 7/11/1997)
51. Tobramycin Sulfate Injection USP
52. Venlafaxine Hydrochloride Tablets (Issued 10/1997, Posted 12/23/1997)
53. Verapamil Hydrochloride Tablets
54. Zolpidem Tartrate Tablets (Issued 9/1997, Posted 10/15/1997)

Labeling (Draft)

1. Clinical Studies Section of Labeling for Prescription Drugs and Biologics-- Content and Format [HTML] or [PDF] (Issued 7/2001, Posted 7/9/2001)
2. Combined Oral Contraceptives - Labeling for Healthcare Providers and Patients [HTML] or [PDF] (Issued 7/2000, Posted 7/7/2000)
3. Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics [HTML] or [PDF] (Issued 6/2000, Posted 6/20/2000)
4. Draft Guidance for Industry on Labeling of OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis) (Issued 6/1998, Posted 7/20/98)
5. Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications [HTML] or [PDF] (Issued 10/2000, Posted 10/25/2000)

Microbiology

1. Format and Content of the Microbiology Section of an Application*

Modernization Act of 1997

1. Changes to an Approved NDA or ANDA [HTML] or [PDF] (Issued 11/1999, Posted 11/19/1999)
2. Classifying Resubmissions in Response to Action Letters (Issued 5/14/1998, Posted 5/14/1998)
3. Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act or Word Version (Issued 11/1998, Posted 11/20/1998)
4. Fast Track Drug Development Programs ? Designation, Development, and Application Review Appendix 2; Appendix 3 consisting of Mapp 6020.3 and SOPP 8405;and Appendix 4 [Appendices are scanned copies, which will be replaced by final versions 11/18] (Issued 11/17/1998, Posted 11/17/1998)
5. Formal Dispute Resolution: Appeals Above the Division Level [HTML] or [PDF] (Issued 2/2000, Posted 3/6/2000)

6. Formal Meetings With Sponsors and Applicants for PDUFA Products [HTML] or [PDF] (Issued 2/2000, Posted 3/6/2000)
7. Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997-Advisory Committees Wordperfect or Acrobat Version (Issued 10/1998, Posted 11/02/98)
8. Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements (Issued 7/1998, Posted 7/20/98)
9. Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions [HTML] or [PDF] (Issued 3/2002, Posted 3/18/2002)
10. National Uniformity for Nonpresciption Drugs - Ingredient Listing for OTC Drugs (Issued 4/1998, Posted 5/5/1998)
11. Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (Issued 5/14/1998, Posted 5/14/1998)
12. Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act [HTML] or [PDF] (Issued 9/1999, Posted 10/4/1999)
    - Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric "Rule," and Their Interaction (Posted 7/27/1999)
13. Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act (Revised 5/1998, Posted 6/12/1998)
14. Standards for Prompt Review of Efficacy Supplements (Issued 5/15/1998, Posted 5/15/1998)
15. Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (Issued 8/1998, Posted 9/15/98)
16. Submitting and Reviewing Complete Responses to Clinical Holds (Revised) [HTML] or [PDF] (Issued 10/2000, Posted 10/25/2000
17. Women and Minorities Guidance Requirements (Issued 7/20/1998, Posted 11/25/1998)

Modernization Act of 1997 (Draft)

1. Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank [HTML] or PDF (Issued 3/2000, Posted 3/28/2000)
2. PET Drug Applications - Content and Format for NDAs and ANDAs [HTML] or [PDF] (Issued 3/7/2000, Posted 3/7/2000)
    - Sample formats for chemistry, manufacturing, and controls sections [PDF] or [Word97]
    - Sample formats for labeling [PDF] or [Word97]
    - Sample formats for Form FDA 356h [PDF] or [Word97]
    - Sample formats for user fee Form FDA 3397 [PDF] or [Word97]
3. Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 [HTML] or [PDF] (Posted 4/4/2001)

Over-the-Counter (OTC) Guidances

1. Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16) (Posted 3/2/1998)
2. General Guidelines for OTC Combination Products (Posted 3/2/1998)

3. Labeling OTC Human Drug Products Using a Column Format [HTML] or [PDF] (Issued 12/2000, Posted 12/18/2000)
4. Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs [Word] or [PDF]
   Example Drug Facts Labels
   - Acetaminophen 120 mg in a Suppository Dosage Form [PDF]
   - Acetaminophen 325 mg in a Suppository Dosage Form [PDF]
   - Acetaminophen 650 mg in a Suppository Dosage Form [PDF]
   - Cimetidine 200 mg in a Tablet Dosage Form [PDF]
   - Clemastine Fumerate 1.34 mg in a Tablet Dosage Form [PDF]
   - Doxylamine Succinate 25 mg Tablet Dosage Form [PDF]
   - Ibuprofen 200 mg in a Tablet/Capsule Dosage Form [PDF]
   - Loperamide HCl in a Liquid Dosage Form [PDF]
   - Loperamide HCl in a Tablet/Caplet Dosage Form [PDF]
   - Miconazole Nitrate Vaginal Products [PDF]
   - Minoxidil Topical Solution 2% for Men and Women [PDF]
   - Minoxidil Topical Solution 5% for Men [PDF]
   - Naproxen Sodium 220 mg in a Tablet/Caplet/Gelcap Dosage Form [PDF]
   - Pseudoephedrine HCl Extended-Release Tablets 120 mg [PDF]
5. Upgrading Category III Antiperspirants to Category I (43 FR 46728-46731) (Posted 3/2/1998)

Over-the-Counter (OTC) Draft

1. Labeling OTC Human Drug Products -Submitting Requests for Exemptions and Deferrals [HTML] or [PDF] (Issued 12/2000, Posted 12/18/2000)
2. Labeling OTC Human Drug Products Updating Labeling in ANDAs [HTML] or [PDF] (2/21/2001)
   - Additional examples 1 (3/19/2001)
   - Additional examples 2 (3/26/2001)
   - Additional examples 3 (3/26/2001)

Pharmacology/Toxicology

1. Carcinogenicity Study Protocol Submissions [HTML] or [PDF] (Issued 5/22/2002)
2. Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products [HTML] or [PDF]
3. Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application* (Posted 3/2/1998)
4. Immunotoxicology Evaluation of Investigational New Drugs [Word] or [PDF] (Issued 10/2002, Posted 10/31/2002)

5. Nonclinical Pharmacology/Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or for the Development of Drugs Intended to Act as Vaginal Contraceptives
6. Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease Evaluation of Drug Toxicity Prior to Phase I Clinical Studies (Posted 3/2/1998)
7. Single Dose Acute Toxicity Testing for Pharmaceuticals

Pharmacology/Toxicology Draft

1. Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities [PDF] (Issued 11/2001, Posted 11/9/2001)
2. Nonclinical Studies for Development of Pharmaceutical Excipients [Word] or [PDF] (Issued 10/2002, Posted 10/2/2002)
3. Photosafety Testing [HTML] or [PDF] (Issued 1/2000, Posted 1/7/2000)
4. Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals [HTML] or [PDF] (Issued 5/2001, Posted 5/7/2001)

Procedural

1. 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (Issued 6/1998, Posted 6/22/1998)
2. Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act [HTML] or [PDF] (Posted 3/27/2000)
3. Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000 [HTML] or [PDF] (Issued 11/1999, Posted 11/29/1999)
4. Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act or Word Version (Issued 11/1998, Posted 11/20/1998)
5. Fast Track Drug Development Programs ? Designation, Development, and Application Review
   Appendix 2; Appendix 3 consisting of Mapp 6020.3 and SOPP 8405;and Appendix 4 [Appendices are scanned copies, which will be replaced by final versions 11/18] (Issued 11/17/1998, Posted 11/17/1998)
6. Financial Disclosure by Clinical Investigators (3/27/2001)
7. Formal Dispute Resolution: Appeals Above the Division Level [HTML] or [PDF] (Issued 2/2000, Posted 3/6/2000)
8. Formal Meetings With Sponsors and Applicants for PDUFA Products [HTML] or [PDF] (Issued 2/2000, Posted 3/6/2000)
9. Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997-Advisory Committees Wordperfect or Acrobat Version (Issued 10/1998, Posted 11/02/98)
10. Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements (Issued 7/1998, Posted 7/20/98)

11. Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions [HTML] or [PDF] (Issued 3/2002, Posted 3/18/2002)
12. Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act [HTML] or [PDF] (Issued 11/2001)
13. Levothyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications [HTML] or [PDF] (Issued 7/2001, Posted 7/12/2001)
14. National Uniformity for Nonprescription Drugs - Ingredient Listing for OTC Drugs (Issued 4/1998, Posted 5/5/1998)
15. Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies [HTML] or [PDF] (Issued 12/2001, Posted 12/10/2001)
    - KI in Radiation Emergencies-Questions and Answers [HTML] or [PDF] (Issued 4/2002, Posted 4/22/2002)
16. Reduction of Civil Money Penalties for Small Entities (Issued 3/20/2001)
17. Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act [HTML] or [PDF] (Issued 9/1999, Posted 10/4/1999)
18. Refusal to File (Issued 7/12/1993, Posted 11/26/99)
19. Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act (Revised 5/1998, Posted 6/12/1998)
20. Special Protocol Assessment [HTML] or [PDF] (Issued 5/2002, Posted 5/16/2002)
21. Standards for Prompt Review of Efficacy Supplements (Issued 5/15/1998, Posted 5/15/1998)

Procedural Draft

1. Applications Covered by Section 505(b)(2) [HTML] or [PDF] (Issued 10/1999, Posted 12/7/1999)
2. Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000 [HTML] or [PDF] (Issued 12/1999, Posted 12/22/1999)
3. Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees [HTML] or [PDF] (2/14/2002)
4. Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution [HTML] or [PDF] (5/14/2001)
5. Guidance for FDA Staff The Leveraging HANDBOOK An Agency Resource for Effective Collaborations [HTML] or [PDF] (Posted 11/16/2001)
6. PET Drug Applications - Content and Format for NDAs and ANDAs (Issued 3/7/2000, Posted 3/7/2000)
    - Sample formats for chemistry, manufacturing, and controls sections
    - Sample formats for labeling
    - Sample formats for Form FDA 356h
    - Sample formats for user fee Form FDA 3397
7. Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (Issued 3/2001, Posted 3/9/2001)
8. Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 [HTML] or [PDF] (Posted 4/4/2001)

9. Submitting Debarment Certification Statements (Issued 10/2/98, Posted 10/2/98)
10. Submitting Marketing Applications According to the ICH/CTD Format: General Considerations [PDF] (Issued 9/2001, Posted 9/5/2001)
11. The Use of Clinical Holds Following Clinical Investigator Misconduct (Issued 4/2002, Posted 8/26/2002)

Small Entity Compliance Guides

1. Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation ? Small Entity Compliance Guide [PDF] (Posted 11/7/2001)

User Fees

1. Classifying Resubmissions in Response to Action Letters (Issued 5/14/1998, Posted 5/14/1998)
2. Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act [HTML] or [PDF] (Issued 6/1999, Posted 6/25/99)
3. Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act [HTML] or [PDF] (Issued 11/2001)
4. Submitting and Reviewing Complete Responses to Clinical Holds (Revised) [HTML] or [PDF] (Issued 10/2000, Posted 10/25/2000)

User Fees (Draft)

1. Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees [PDF] (2/21/2001)

Also see Current Good Manufacturing Practice Regulations

Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations
(Posted 8/11/1997)

[Accessibility]

12/17/2001

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117 Results

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* denotes when site was updated.
Material typically becomes available here 6 months after collection. See FAQ.

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					Apr 13, 2001	Jun 01, 2002	Aug 12, 2003	Jun 17, 2004	Feb 12, 2005	Feb 21, 2006	Jar
					May 09, 2001	Aug 10, 2002	Dec 03, 2003 *	Jun 28, 2004	Feb 28, 2005	May 16, 2006 *	Jar
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